

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

930092-2008

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed  
name \_\_\_\_\_

Application Number

10/520,231

Filed

27 May 2003

First Named Inventor

TALJAARD

Art Unit

3732

Examiner

MAI, Hao D.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.  
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
 (Form PTO/SB/96)

☐ attorney or agent of record.  
 Registration number \_\_\_\_\_

☒ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 48,104

/Howard C. Lee/

Signature

Howard C. Lee

Typed or printed name

(202) 292-1539

Telephone number

11 June 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## **REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW**

### **I. Status of claims**

Claims 1, 2, 5-7, 11-14, 18, 22 and 23 are pending in this application. There are no amendments after final to be considered. The applicants request reconsideration of the 35 U.S.C. 103(a) rejection of the pending claims over Karasic and Bertoc made in the final rejection of 11 January 2010 ("the Office Action").

### **II. Basis for clear error in 35 U.S.C. 103(a) rejection**

Claims 1, 2, 5-7, 11-14, 18, 22 and 23 were rejected as allegedly being obvious over Karasic (U.S. Patent 6,805,127) in view of Bertoch (U.S. Patent 6,755,191).

The applicants' believe that the rejection is in error because the applicants' claim terms have been interpreted by giving them the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997)(emphasis added) and MPEP 904.01.

As noted in the recent *Suitco* decision, "The PTO's construction here, though certainly broad, is unreasonably broad. The broadest-construction rubric coupled with the term "comprising" does not give the PTO an unfettered license to interpret claims to embrace anything remotely related to the claimed invention. Rather, claims should always be read in light of the specification and teachings in the underlying patent. See *Schreiber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 217 (1940)." *In re Suitco* (Fed. Cir. – April 14, 2010).

The applicants explain below why the claim interpretation made in the Office Action would not be recognizable to those of ordinary skill in the art and why the obviousness rejection is therefore in error.

#### **A. Biased Apart Tooth Engaging Portions Not Taught by Karasic and Bertoch**

The Office Action (paragraph 2) alleges that Karasic discloses a first patient engaging portion and a second engaging portion wherein "...the two portions are being *biased apart* to provide a working gap between". It is respectfully submitted that this interpretation is error.

Karasic does disclose two opposing tooth engaging portions (mouth guards 14 and 24),

but said portions are not *biased apart*. Both mouth guards are connected or connectable to a fastener (12), but the fastener merely retains the two mouth guards in a stationary position relative to one another *without biasing said mouth guards apart*. At no time does the fastener exert an opening force on the two mouth guards, as it is merely intended to retain the mouth guards in a required stationary position.

The biased apart tooth engaging portions of the claimed medical tube retaining device alleviates the need for the complicated and impractical fastening arrangement as disclosed in Karasic.

In addition, the inherent outward bias in the retaining tube of the invention will result in the provision of a working gap between the tooth engagement portions whilst an endotracheal tube is being inserted into an oral cavity of the patient. This allows the mouth of the patient to be closed in a more relaxed condition once the tube has been inserted. Excessive closure of the mouth, and thus potential damage of the tube, is prevented by way of biting blocks provided on the tooth engagement portions. The biased apart tooth engaging portion, in combination with the bite blocks, therefore allows the medical tube retaining device to be displaceable between two discrete positions, which is not achievable by the device disclosed in Karasic.

**B. Medical Tube Guide Means Not Taught by Karasic and Bertoch**

The Office Action (paragraph 2) alleges that Karasic discloses “...a medical tube guide means, e.g. the tongue retractor holder 62 or throat opener channel/holder 42, either of which is capable of holding a medical tube...”. It is respectfully submitted that this interpretation is also in error.

The tongue retractor holder 62 disclosed in Karasic is in the form of a rectangular or U-shaped arch provided on the lower mouth guard, and is provided for “slideably engaging the tongue depressor” (Karasic: col. 4, line 20).

A tongue depressor is a device for use in depressing the tongue, and illuminating the throat of the patient (Karasic: col. 6, line 45). It is submitted that a tongue depressor cannot be interpreted as being a medical tube, and that the tongue retractor holder 62 can therefore not be interpreted as a medical tube guide means; i.e., the interpretation made in the Office Action is precisely the type of overbroad embracing of anything remotely related to the invention which was admonished against in *Suitco*.

In particular, the aperture defined by the tongue retractor holder 61 is in the form of an elongate slot, and is particularly unsuitable for receiving a medical tube, which has a circular circumference. It is

submitted that the collocation of Karasic and Bertoch to arrive at the securing means for use in limiting longitudinal displacement of the medical tube is not obvious, as the disclosure in Karasic is already too far removed from the medical tube guide means claimed in the present invention.

Moreover, the throat opener channel/holder 42 disclosed in Karasic is in the form of “...*a first wall, a second wall, and a passageway connecting the first and second walls*” (col 4., line 7). The throat opener holder(s)/channel(s) 42 are provided for receiving a throat opener. Karasic is silent as to the exact structural details of the throat opener, and it can only be assumed by a person skilled in the art that the throat opener will be in the form of a device like a Finnoshetti retractor, a Tufftier retractor, a Crowe Davis Mouth Gag or a Jennings Mouth Gag.

One of ordinary skill in the art would appreciate that none of these throat openers can be interpreted as being medical tubes, and the throat opener holder(s)/channel(s) are merely provided to anchor the throat opener. It is unclear that Karasic (col. 7, line 7) even refers to a throat opener, but when a person skilled in the art considers the figures accompanying the Karasic specification, it would be readily apparent to the artisan that the structure and configuration of the throat opener holder/channel 42 will not be suitable for receiving a medical tube.

It should also be noted that neither the tongue retractor holder 62, nor the throat opener channel 42, will be able to securely immobilize a medical tube as envisaged in the present invention. Apart from the arguments already set out above, this is also due to the fact that the retractor holder 62 and throat opener channel 42 both include apertures of limited depth, which will allow undesirable angular displacement or pivoting of a medical guide tube relative to these structures. In the present invention the medical tube guide means is in the form of an elongate channel that will prevent angular displacement of a medical tube relative to the tube guide means.

More particularly, the medical tube guide means is configured to “...*immobilize the medical tube 12 in a desired position...*”, which will not be possible when the tongue retractor holder 62 or throat opener channel 42 are used as medical tube guide means.

**C. Bite Block Not Taught by Karasic and Bertoch**

The presently claimed medical tube retaining device includes at least one bite block extending from at least one of the patient engaging portions for preventing a patient from exerting a compressive force on the medical tube. The Examiner alleges that Karasic discloses “...*at least one bite block, e.g. structure 34/36 or 40...*”. The purpose of the bite blocks is to prevent the patient from biting down onto the medical tube.

However, the bite blocks still allow the patient to substantially close his or her mouth against the bias of the patient engaging formations. As mentioned above, the bite block and the inherent bias of the patient engaging formations, in combination, allow the device to be displaceable between an open position in which maximum access is provided to the oral cavity of the patient via a working gap, and a closed position in which the patients' jaws are at least partially closed.

Structure 34/36 refers to the post and tube arrangement of the fastening means 12 utilized in the Karasic device. Structure 34/36 is secured in a selected, stationary position and therefore does not act as a bite block as described above. Even if the telescopic structure 34/36 is fully retracted, it will not allow the closing of the device to the extent facilitated by the bite blocks used in the present invention, as a minimum opening gap will always be dictated by the length of the tube 34 and post 36 of the structure.

It is therefore respectfully submitted that structure 34/36 cannot be interpreted as being a bite block. Structure 40, i.e. the tongue retractor holder as discussed above, is neither intended nor configured to perform as a bite block, and it is submitted that it is also incorrect to interpret structure 40 as a bite block.

#### **D. Closing**

As obviousness requires that all elements of the applicants' claimed invention be addressed by the references of record, any one of the deficiencies for the combination of Karasic and Bertoch would be sufficient to overcome the obviousness rejection of record.

However, as the combination of Karasic and Bertoch do not teach (1) a biased apart tooth engaging portion; (2) a medical tube guide means; or (3) a bite block, the combination of Karasic and Bertoch clearly do not establish that the applicants' claimed medical tube retaining device is *prima facie* obvious.

NOTE:

Although not required to proceed to Appeal, should the present rejections be maintained, in order to expedite prosecution, the applicants' offer the entry, via an Examiner's Amendment, the following phrase at the end of claim 1: ---the first and second patient engagement portions meet at an apex, and are pivotably displaceable relative to one another.--- (support for this amendment can be found in the specification on page 5, line 19 – “The first and second patient engagement portions may be in the form of a pair of arms having tooth engagement portions.”; page 6, line 8 – “The pair of arms may meet at an apex, which apex forms a support point for the medical tube guide means.”; and page 6, line 11 – “The pair of arms may be pivotably displaceable relative to one another.”